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# 510(k) Summary

## Applicant Information


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|---|---|
| **Applicant Name:** | Rotation Medical, Inc. |
| **Applicant Address:** | 15350 25th Avenue North, Suite 100<br>Plymouth, MN 55447 |
| **Telephone:** | 763-746-7521 |
| **Fax:** | 763-746-7501 |
| **Contact Person:** | Gail Schroeder<br>Director, Quality Assurance and Operations |
| **Date Prepared:** | August 27, 2013 |


## Name of Device

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| **Device Common Name:** | Nondegradable soft tissue to bone fixation staple |
| **Device Trade Name:** | Rotation Medical Bone Staple (RMB Staple) |
| **Device Classification Name:** | Bone Fixation Fastener<br>888.3040<br>Class II<br>MBI |

## Legally Marketed Devices to Which Substantial Equivalence is Claimed

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| **Predicate Device(s):** | Ethicon SecurestrapTM 5mm Absorbable Strap Fixation Device, K093845; Ethicon, Inc.<br><br>SwiveLock Anchors, K101823 Arthrex, Inc. |

## Description of the Device

The RMB Staple is a sterile, single use polymer strap with cleat tips. RMB Staple is composed of PEEK material. The RMB Staple is used in conjunction with an orthopedic manual staple driver from Rotation Medical. (Note: Rotation Medical's orthopedic manual staple driver is a Class I exempt device pursuant to 21 CFR 888.4540 and is not the subject of this submission).

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## Intended Use

The RMB Staple is indicated for fixation of soft tissue grafts during rotator cuff repair.

## Summary/Comparison of Technical Characteristics

The RMB Staple and the predicate device, Ethicon Securestrap™, have similar indications for use and physical design. Both devices are indicated for the fixation of prosthetic material, and are comprised of a polymer strap with barbed ends. The Securestrap™ is optimized for soft tissue fixation, while the RMB Staple is optimized for fixation to bone. The RMB Staple and the predicate device, SwiveLock Anchor, are made of the same material, PEEK, and are used similarly to aid in the management of tendon injuries by affixing a prosthetic material to bone. The RMB Staple directly affixes the prosthetic material to bone, while the predicate SwiveLock indirectly affixes the prosthetic material by proving an anchor point for sutures which have been sewn to/through the prosthetic material.

RMB Staple has been evaluated in a number of *in vitro* and *in vivo* tests to assess its safety/biocompatibility and substantial equivalence to the predicates, including: cytotoxicity, sensitization, intracutaneous reactivity, toxicity, and animal testing with histology. In addition, *in vivo* and in vitro strength and retention were also assessed.

## Conclusion

The device passed all applicable FDA Blue Book Memorandum G95-1 and ISO 10993-1 testing for the biological evaluation of medical devices. The results of the *in vitro* product characterization studies, bench testing and *in vitro* and *in vivo* biocompatibility studies, as well as the animal efficacy study demonstrate that the RMB Staple is safe and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

August 29, 2013

Rotation Medical, Inc.
Gail Schroeder
Director, Quality Assurance and Operations
15350 25th Avenue North, Suite 100
Plymouth, Minnesota 55447

Re: K131635
Trade/Device Name: Rotation Medical Bone Staple (RMS Staple)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 23, 2013
Received: July 24, 2013

Dear Ms. Schroeder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): ____

Device Name: Rotation Medical Bone Staple (RMB Staple)

Indications for Use:

The RMB Staple is indicated for fixation of soft tissue grafts during rotator cuff repair.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131635